

THE FILED

U.S. DISTRICT COURT
EASTERN DIST. TENN.

66. _____ DEPT. 622 AK

No.:

3:17-cr-398
Matice/Shirley

[FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)]

ORIGINAL

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF TENNESSEE
NORTHERN DIVISION

UNITED STATES)
OF AMERICA ex rel.)
CYNTHIA NIENDORFF,)
SHANNON SKIPPER,)
and RUSSELL SMITH)

Plaintiffs,)

No.:

v.)

ANESTHESIA SERVICES)
ASSOCIATES, PLLC,)
a Tennessee Limited Liability)
Company doing business as)
COMPREHENSIVE PAIN)
SPECIALISTS; PHYMED)
MANAGEMENT, LLC, a)
Tennessee Limited Liability)
Company; and DOES 1 TO 50,)

Defendants.)

PLAINTIFFS' COMPLAINT FOR DAMAGES FOR:

- (1) VIOLATIONS OF FALSE CLAIMS ACT (31 U.S.C. § 3729(a)(1)(A));
- (2) VIOLATIONS OF FALSE CLAIMS ACT (31 U.S.C. § 3729(a)(1)(B))

DEMAND FOR JURY TRIAL

[FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §
3730(b)(2)]

Qui tam plaintiffs CYNTHIA NIENDORFF (“Niendorff”), SHANNON SKIPPER (“Skipper”), and RUSSELL SMITH (“Smith”) (collectively, Niendorff, Skipper, and Smith are “Plaintiffs”) respectfully allege as follows:

I. INTRODUCTION

1. In this action, Plaintiffs allege that defendants ANESTHESIA SERVICES ASSOCIATES, PLLC, a Tennessee Limited Liability Company doing business as COMPREHENSIVE PAIN SPECIALISTS (“CPS”), PHYMED MANAGEMENT, LLC, a Tennessee Limited Liability Company (“PhyMed”); and DOES 1 to 50 (collectively, CPS, PhyMed, and DOES 1 to 50 are “Defendants”) are liable under 31 U.S.C. § 3729, et seq. (the “False Claims Act”) for submitting in excess of a million dollars per month in unnecessary comprehensive definitive drug testing panels to the Medicare program. Because Plaintiffs believe that Defendants’ wrongful conduct will continue to damage both plaintiff UNITED STATES OF AMERICA (“United States” or “United States of America”) and patients who do not know any better, Plaintiffs allege that Defendants are liable under the False Claims Act, as described in more detail below.

II. JURISDICTION AND VENUE

2. Plaintiffs bring this action on behalf of the United States under the provisions of the False Claims Act. Accordingly, this Court has original subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1345.

3. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a). Jurisdiction is proper over the defendants because Defendants can be found in, reside in, and have transacted business within this Court's jurisdiction.

4. Venue is appropriate in this judicial district under 31 U.S.C. § 3732(a) because Defendants reside in, can be found, and transact business in this judicial district.

III. THE PARTIES

5. The United States is the plaintiff in this action. Plaintiffs are seeking recovery on the United States' behalf.

6. Niendorff is an individual and citizen of the United States of America residing in Knox County, Tennessee. Niendorff is an anesthesiologist and pain specialist licensed to practice medicine in the State of Tennessee. Niendorff has been an anesthesiologist for various CPS clinics in Tennessee (Cleveland, Chattanooga, Knoxville, Lenoir City) from approximately November 2015 to the present (as of the date this complaint was signed).

7. Skipper is an individual and citizen of the United States of America residing in Bradley County, Tennessee. Skipper was a consultant and vice president of business development at CPS from approximately January 2013 to July 2017.

8. Smith is an individual and citizen of the United States of America residing in Bradley County, Tennessee. CPS had a contractual relationship with Smith that originated in or around July 2013 and was terminated in June 2017. Smith owned and operated five clinics in Tennessee (Cleveland, Chattanooga, Knoxville, Athens, Lenoir City), and all of these clinics went under the umbrella of CPS. Smith managed these five clinics pursuant to his contractual relationship with CPS.

9. CPS is a physician-owned company, formed in 2005 in Hendersonville, Tennessee, with more than 60 clinics in 12 states across the country, including 26 in Tennessee and 7 in Eastern Tennessee in this district. In connection with these clinics, CPS also operates a CLIA-waived and regulated laboratory in Brentwood, Tennessee that performs drug screens. ("CLIA" = Clinical Laboratory Improvement Amendments.) CPS has operated as a subsidiary of PhyMed since on or around November 16, 2015.

10. PhyMed is a physician-owned company comprised of anesthesia, pain management, and critical care professionals. Formed in 1994, and based in Nashville, Tennessee, PhyMed is one of the largest physician-led anesthesia service companies in the United States, with more than 350 certified clinicians in multiple states, including Tennessee. PhyMed acquired CPS on or around November 16, 2015.

11. The allegations and transactions upon which Plaintiffs base this complaint were not publicly disclosed in a federal criminal, civil, or administrative hearing in which the government or its agent is a party. Nor have they been disclosed in a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation; or in the news media.

12. Plaintiffs are the original source of information in this complaint. Plaintiffs have voluntarily disclosed to the government the information on which the allegations and transactions in this complaint are based. Plaintiffs' disclosure to the government was contemporaneous with the filing of the complaint, and Plaintiffs acted on their own accord, without compensation or legal obligation to provide the information.

13. Plaintiffs' knowledge of the allegations and transactions in this complaint are derived from their own efforts and labor. Plaintiffs' knowledge is not based on publicly disclosed information, and their knowledge preceded any public disclosure of the allegations and transactions in this complaint.

14. Plaintiffs are ignorant of the true names and capacities, whether individual, partnership, corporate, associate or otherwise, of defendant DOES 1 through 50, inclusive, and therefore sue these defendants by fictitious names. Plaintiffs are informed and believe, and on that basis allege, that these fictitiously named defendants, and each of them, are in some manner responsible and liable for

the acts and/or damages alleged in this Complaint. Plaintiffs will seek leave of court to amend this Complaint to show the fictitiously named defendants' true names and capacities when they have been ascertained. Plaintiffs are informed and believe, and on that basis allege, that each of the fictitiously named defendants were, in some manner, responsible for the occurrences herein alleged, and proximately caused the damages alleged in this Complaint.

15. Plaintiffs are informed and believe, and on that basis allege, that at all relevant times (except where pled otherwise) Defendants were acting as the agents, servants, employees, partners, and/or joint venturers of each other. Defendants maintain such unity of interest that separate personalities of each defendant no longer exist. In doing the wrongful acts alleged herein, each defendant was acting in the full course and scope of such agency, employment, partnership, and/or joint venture with the full knowledge, consent, permission, and ratification, either express or implied, of each of the other defendant, and as such, was acting as the alter ego of each other defendant. Adherence to the fiction of the separate existence of each defendant would permit an abuse of the corporate privilege, sanction fraud, and promote injustice.

IV. THE FALSE CLAIMS ACT

16. The federal False Claims Act was originally enacted during the Civil War. Congress substantially amended the False Claims Act in 1986 to enhance the

ability of the United States to recover losses sustained due to fraud against it.

17. On May 20, 2009, Congress amended and renumbered the False Claims Act again pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (“FERA”).

18. The False Claims Act, under the FERA amendments, sets forth liability, in pertinent part, for any person who:

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .

31 U.S.C. §§ 3729(a)(1)(A)-(B)(emphases added).

19. The False Claims Act further provides, in pertinent part, that “knowing” and “knowingly:”

(A) mean that a person, with respect to information—

- (i) has actual knowledge of the information;
- or (ii) acts in deliberate ignorance of the truth or falsity of the information; or
- (iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud.

31 U.S.C. §§ 3729(b)(1)(A)-(B).

And the term, “claim:”

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

- (i) is presented to an officer, employee, or agent of the United States; or

- (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
 - (I) provides or has provided any portion of the money or property requested or demanded; or
 - (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or other property which is requested or demanded; and
- (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property; . . .

31 U.S.C. §§ 3729(b)(2)(A)-(B).

20. Under Section 4(f) of the FERA amendments, 31 U.S.C. § 3729(b)(1)(A) (formerly 31 U.S.C. § 3729(a)(1)) applies to conduct on or after May 20, 2009. 31 U.S.C. § 3729(b)(1)(B) (formerly 31 U.S.C. § 3729(a)(2)) applies to all claims that were pending on or after June 7, 2008.

21. 31 U.S.C. § 3729(a)(1) of the pre-FERA False Claims Act provides that any person who “knowingly presents, or causes to be presented, to an officer or employee of the United States . . . a false or fraudulent claim for payment or approval” is liable for a civil penalty of “not less than \$5,000 and not more than \$10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.” 31 U.S.C. § 3729(a)(1).

22. 31 U.S.C. § 3729(a)(2) of the pre-FERA False Claims Act provides liability for any person who “knowingly makes, uses, or causes to be made or used,

a false record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(2).

23. The False Claims Act allows any person having information about a possible violation of the False Claims Act to bring an action on behalf of the United States, and to share in any recovery. 31 U.S.C. §§ 3730(b), (d)(1). The False Claims Act also awards reasonable attorneys’ fees and costs to the prevailing qui tam plaintiff as a matter of right. 31 U.S.C. § 3730(d)(1).

V. THE MEDICARE AND MEDICAID PROGRAMS

24. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, et seq., establishes the Health Insurance for the Aged and Disabled Program, commonly referred to as the Medicare Program (the “Medicare Program” or “Medicare”).

25. The Medicare Program is comprised of four parts: A, B, C, and D.

26. Medicare Part B provides federal government funds to help pay for professional services performed by physicians and clinical diagnostic laboratory tests, provided to Medicare beneficiaries, so long as such services are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” *See* 42 U.S.C. §§ 1395x(q), (r), (s)(1), (3), 1395y(a)(1)(A).

27. Physicians’ services and diagnostic tests are listed as covered medical and other health services under Medicare Part B. *See* 42 C.F.R. §§ 410.10(a), (e),

410.12.

28. Healthcare providers must make certain certifications in connection with the services provided, one of which is sometimes referred to as the “medical necessity” requirement. *See* 42 U.S.C. § 1395f(a)(3).

29. The certifications, including the “medical necessity” requirement, are described in 42 U.S.C. § 1395f, in relevant part, as follows:

(a) Requirement of requests and certifications. Except as provided in subsections (d) and (g) and in section 1876 [42 USCS § 1395mm], payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1866 [42 USCS § 1395cc] and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service;

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner or direct clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician, or, in the case of services described in subparagraph (C), a physician enrolled under section 1866(j) [42 USCS § 1395cc(j)], certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that-- . . .

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled

nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1861(e) [42 USCS § 1395x(e)(6) and 9)] prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services; . . .

(3) with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose, except that (A) such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations, and (B) the first such certification required in accordance with clause (A) shall be furnished no later than the 20th day of such period; . . .

To the extent provided by regulations, the certification and recertification of paragraph (2) shall be deemed satisfied where, at a later date, a physician, nurse practitioner, clinical nurse specialist, or physician assistant (as the case may be) makes certification of the kind provided in subparagraph (A), (B), (C), or (D) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. . . .

42 U.S.C. §§ 1395f(a)(1)-(3), flush language.

30. According to 42 C.F.R. § 412.46(b): "No presumptive weight shall be

assigned to the physician's order under § 412.3 or the physician's certification under Subpart B of Part 424 of the chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act [42 U.S.C. § 1395y, *infra*]. A physician's order or certification will be evaluated in the context of the evidence in the medical record.”

31. Providers must assure that they provide economical medical services, and then, only when, and to the extent that they are medically necessary. 42 U.S.C. § 1320c-5(a)(1).

32. Medicare regulations exclude from payment services that are not reasonable and necessary for any number of reasons. *See generally* 42 C.F.R. § 411.15(k)(1)-(16).

33. Diagnostic tests are payable only when the physician who is treating the beneficiary for a specific medical problem uses the results in such treatment. 42 C.F.R. § 410.32(a).

34. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and by contributions from the federal treasury. Eligible individuals may enroll in Part B to obtain benefits in return for payments of monthly premiums as established by the United States Department of Health & Human Services (“HHS”). *See* 42 U.S.C. §§ 1395o, 1395p, 1395q, 1395r, 1395s.

35. Payments under the Medicare Part B program are often made directly

to service providers, rather than to the patient (the “beneficiary”). This occurs when the provider accepts assignment of the right to payment from the beneficiary. In that case, the provider submits his bill directly to Medicare for payment.

36. The Secretary of HHS administers the Medicare Program through the Centers for Medicare & Medicaid Services (“CMS”), an operating division of HHS.

37. CMS, in turn, contracts with Medicare Administrative Contractors, formerly known as Part B Carriers (hereinafter, “MACs”) to administer, process, and pay Part B claims from the Federal Supplementary Medical Insurance Trust Fund (the “Medicare Trust Fund”). In this capacity, MACs act on behalf of CMS.

38. The Medicare Program, through the MAC, pays a significant portion of every claim. The Medicare beneficiary, or his or her supplemental insurance carrier, is required to pay the balance owed the provider. The beneficiary’s payment is sometimes referred to as a “co-payment.” Beneficiaries also pay deductibles.

39. All healthcare providers must comply with applicable statutes, regulations, and guidelines in order to be reimbursed by Medicare. A provider has a duty to have knowledge of the statutes, regulations, and guidelines regarding coverage for the Medicare services.

40. Title XIX to the Social Security Act establishes the Medicaid

Program. *See generally* 42 U.S.C. §§ 1396, et seq.

41. Under the Medicaid Program, the federal government provides matching funds to states to enable them to provide medical assistance to residents who meet certain eligibility requirements.

42. Although states are not required to participate, those that do must comply with federal Medicaid laws. *See, e.g.*, 42 U.S.C. §§ 1396-1, 1396a.

VI. CAHABA LOCAL COVERAGE DETERMINATIONS

43. The Medicare contractor for the State of Tennessee is Cahaba Government Benefit Administrators, LLC (“Cahaba”) on behalf of CMS.

44. Cahaba issued Local Coverage Determinations (“LCD”) regarding qualitative drug testing.

45. Two of Cahaba’s LCDs entitled “Pathology and Laboratory: Qualitative Drug Testing (L34501)” and “Pathology and Laboratory: Qualitative Drug Testing (L35920)” are effective as to services performed on or after October 1, 2015.

46. According to LCD L34501:

Coverage Indications, Limitations, and/or Medical Necessity *Background*

A qualitative drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for broad qualitative screening, as blood is relatively insensitive for many common drugs.

Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound. Drugs or classes of drugs are commonly assayed by qualitative testing. A qualitative test may be followed by confirmation with a second method, only if there is a positive or negative finding inconsistent with the setting of a symptomatic patient.

Examples of drugs or classes of drugs that are commonly assayed by qualitative tests, followed by confirmation with a second method, are: alcohols, amphetamines, barbituates/sedatives, benzodiazepines, cocaine and metabolites, methadone, antihistamines, stimulants, opioid analgesics, salicylates, cardiovascular drugs, antipsychotics, and antidepressants.

Most toxicological diagnoses and therapeutic decisions are made based on historical or clinical considerations:

1. Laboratory turnaround time can often be longer than the critical intervention time course of an overdose;
2. For many toxins there are no established cutoff levels of toxicity, making interpretation of the results difficult.

Qualitative screening panels should be used when the results will alter patient management or disposition. The clinical utility of drug tests in the emergency setting is limited since most therapy for drug poisonings is symptom directed and supportive.

Indications

Medicare will consider performance of a qualitative drug test reasonable and necessary:

1. When a patient presents with suspected drug overdose and one or more of the following conditions:
 - A. Unexplained coma;
 - B. Unexplained altered mental status in the absence of a clinically defined toxic syndrome or toxidrome;

- C. Severe or unexplained cardiovascular instability (cardiotoxicity);
- D. Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome;
- E. Testing on neonates suspected of prenatal drug exposure;
- F. Seizures with an undetermined history.
- 2. For monitoring patient compliance during active treatment for substance abuse or dependence.
- 3. In patients on chronic opioid therapy:
 - A. In whom illicit drug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed drug regimen is suspected and documented in the medical record; and/or
 - B. In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse.
- 4. In patients with chronic pain to:
 - A. Determine the presence of other substances prior to initiating pharmacologic treatment;
 - B. Detect documented suspected non-adherence to the plan of care.
 - C. Periodic random (not routine) testing to confirm adherence to pharmacologic treatment plan.
- 5. In patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication.

Confirmation of drug testing (80102) is indicated when:

- 1. The results of the qualitative screen are presumptively positive; or
- 2. Results of the qualitative screen are negative and this negative finding is inconsistent with the patient's medical history.

Limitations

- 1. It is considered not reasonable or necessary to test for the same drug with both a blood and a urine specimen

simultaneously.

2. CPT codes 80150 through 80299 are examples of quantitative therapeutic assays for specific drugs. These codes should not be billed when only qualitative screening is performed.
3. Drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) is not covered.
4. Routine “per visit” drug testing in chronic pain patients is noncovered.

See generally LCD L34501.

47. According to LCD L35920:

Coverage Indications, Limitations, and/or Medical Necessity

Background:

Definitive/Quantitative/Confirmation (hereafter called ‘definitive’ UDT) – Used when medically necessary to identify specific medications, illicit substances and metabolites; Reports the results of drugs absent or present in concentrations of ng/ml; Limited to GC-MS and LC-MS/MS testing methods only.

Specimen Validity Testing – Urine specimen testing to ensure that it is consistent with normal human urine and has not been adulterated or substituted; May include pH, specific gravity, oxidants and creatinine.

Point of Care Testing (POCT) – Used when medically necessary by clinicians for immediate test results for the immediate management of the patient; Available when the patient and physician are in the same location; IA test method that primarily identifies drug classes and a few specific drugs; Platform consists of cups, dipsticks, cassettes, or strips; Read by the human eye.

Standing Orders – Test request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits; Individualized orders for certain patients for pre-determined tests based on historical use, risk and community trend patient profiles; Clinician can alter the standing order. Note: A “profile” differs from a “panel” in that a profile responds to the clinical risks of a particular patient, whereas a panel encourages unnecessary or excessive testing when no clinical cause exists.

Blanket Orders – Test request that is not for a specific patient; rather, it is an identical order for all patients in a clinician’s practice without individualized decision making at every visit.

Definitive Urine Drug Testing (UDT): Gas Chromatography coupled with Mass Spectrometry (GC-MS) and High Performance Liquid Chromatography coupled with Tandem Mass Spectrometry (LC-MS/MS) use the separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry. Both methodologies require on-site highly trained experts in this technology and interpretation of results. While these tests require different sample preparation and analytical runs, they identify all specific drugs, metabolites, and most illicit substances and report the results as absent or present in concentrations of ng/mL.

Quantification should not be used to determine adherence with a specific dosage or time of dose of a pain medication or illicit drug for clinical purposes. Rather, the use of quantitative drug data may be important for many reasons such as in a different patient assessment. For example, when several opioids are present in the urine of a patient prescribed a single opioid, quantification may help the clinician decide whether the presence of the other opioids is consistent with metabolism of the prescribed opioid, opioid contamination during manufacturing, or if more than one drug within a class is being used.

Quantification may also provide information in the setting of illicit drug use. Serial creatinine-corrected quantitative values

may assist in the differential assessment of ongoing drug use or cessation of drug use with continued drug excretion.

GC-MS can only be performed on molecules that are volatile. If the test drug is not volatile, it must be modified or derivatized to a volatile form. To derivatize, the test drug must be extracted from the urine, eluted from the extraction device, concentrated, and then reacted with a chemical reagent to make a volatile product. Each drug class may require a different derivatizing agent. For patients on multiple classes of medications, laboratories using GC procedures must make different volatile derivatives in order to perform comprehensive testing. Since a column may not be able to separate more than one class of compounds, multiple chromatographic runs on different column types may be required to monitor multiple drug classes. Newer GC-MS instruments use tandem systems. GC-MS methodology allows for the testing of multiple substances but differs in ease of run.

LC-MS/MS is roughly 100 times more sensitive and selective, involves less human steps, provides quicker turn-around time, uses less specimen volume and can test for a larger number of substances when compared to GC-MS. After sample preparation, it is injected into the LC-MS/MS. The sample has to undergo hydrolysis to break the glucuronide bond that frees the drug and drug metabolites. Hydrolysis is followed by multiple additional steps including protein precipitation, centrifugation and purification. Deuterium-labeled isotopic internal standards are added to quantify the drugs and drug metabolites.

The sample is injected when the mobile phase is flowing through the chromatographic column. Each drug and drug metabolite interacts with the mobile phase and stationary phase differently and moves at different speeds depending on their chemical properties. In other words, each analyte elutes at different times. Specific drugs are identified by their retention time and mass spectrum of each peak, and quantified against isotopic internal standards for each drug and metabolite. Each drug peak has a minimum of two mass transitions, which the

technician has to compare to drug standards (calibrators) in order to ensure identification.

Indications

Definitive UDT is reasonable and necessary for the following circumstances:

1. Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT screen;
2. Definitively identify specific drugs in a large family of drugs;
3. Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;
4. Identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan);
5. Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan;
6. Rule out an error as the cause of an unexpected presumptive UDT result; Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; and
7. Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.

Definitive UDT may be reasonable and necessary based on patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions. The clinician's rationale for the definitive UDT and the tests ordered must be documented in the patient's medical record.

Definitive UDT Panels

At the current time, physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record. Some labs offer comprehensive definitive drug testing panel (CDDP) of 40 or more drugs. It is not reasonable and necessary to bill individual billing codes for this comprehensive testing.

Limitations

The following are non-covered services:

1. Blanket Orders
2. Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the physician may not need to order definitive testing (e.g., the patient admits to a particular drug and the clinician is satisfied that he or she knows everything he or she needs to know, or the IA cut-off is sufficiently low that the physician is comfortable with the test result).
3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary. Physician-defined standing orders for pre-determined drug panels according to specific patient profiles for a limited sequential period may be reasonable and necessary and must be documented in the patient's medical record.
4. Individual definitive CPT codes when a CDDP is ordered.
5. Confirmation/definitive identification of a

presumptive UDT negative result is not reasonable and necessary except when a patient on a prescribed medication should have had a presumptive positive result.

6. IA testing, regardless of whether it is qualitative or semi-quantitative, may not be used to “confirm” or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other CLIA-waived methods. Semi-quantitative IA testing provides a presumptive test (numerical) result. Definitive UDT provides specific identification and/or quantification by GC-MS or LC-MS/MS.
7. Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.
8. UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.
9. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.
10. CDDP panels are non-covered.

See generally LCD L35920 (emphases added in underline).

VII. BACKGROUND ALLEGATIONS

48. In 2012, CPS opened a CLIA-waived and regulated laboratory in Brentwood, Tennessee that performs drug screens for patients being considered for opioid therapy.

49. The physicians who practice at CPS clinics must send all specimens to the Brentwood laboratory for processing. There is no point-of-care testing done in the clinics.

50. At all relevant times, it was CPS' policy to have all drug screen testing done at the Brentwood laboratory.

51. At all relevant times, it was CPS' policy to have all specimens receive a qualitative screening for common drug classes—i.e., positive/negative.

52. At all relevant times, it was CPS' policy and practice, regardless of the medical documentation, to always confirm positive drug screenings via LCMS.

53. CPS had actual and constructive knowledge of LCD L35920, which provides that the “reasonable and necessary” requirement for reimbursement under Medicare Part B is not satisfied when labs bill individual billing codes for comprehensive testing; for confirmation/definitive identification of a presumptive UDT negative result; and for CDDP panels.

54. Nonetheless, from at least 2012 and continuing to the present, CPS sent every patient's UDTs in for CDDP panels at the Brentwood, Tennessee laboratory, even when the UDT results were actually and presumptively negative. Upon information and belief, PhyMed ratified this practice since it acquired CPS on or around November 16, 2015.

55. The following are illustrative examples:

- a. For Medicare beneficiary B.E., on or around August 16, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

- b. For Medicare beneficiary B.E., on or around September 13, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- c. For Medicare beneficiary B.E., on or around October 11, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- d. For Medicare beneficiary B.E., on or around November 3, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- e. For Medicare beneficiary B.E., on or around December 2, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- f. For Medicare beneficiary B.E., on or around January 5, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

- g. For Medicare beneficiary B.E., on or around March 1, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- h. For Medicare beneficiary D.B., on or around November 10, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- i. For Medicare beneficiary D.B., on or around January 11, 2017, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- j. For Medicare beneficiary D.B., on or around February 9, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- k. For Medicare beneficiary D.B., on or around March 6, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

- l. For Medicare beneficiary D.B., on or around March 30, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- m. For Medicare beneficiary D.B., on or around April 3, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- n. For Medicare beneficiary C.R., on or around August 5, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- o. For Medicare beneficiary C.R., on or around October 4, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- p. For Medicare beneficiary C.R., on or around January 6, 2017, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

- q. For Medicare beneficiary C.R., on or around March 3, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- r. For Medicare beneficiary C.R., on or around April 26, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- s. For Medicare beneficiary C.R., on or around June 20, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- t. For Medicare beneficiary A.V., on or around July 12, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- u. For Medicare beneficiary A.V., on or around July 19, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

- v. For Medicare beneficiary A.V., on or around September 9, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- w. For Medicare beneficiary A.V., on or around October 4, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- x. For Medicare beneficiary A.V., on or around December 12, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- y. For Medicare beneficiary A.V., on or around February 13, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.
- z. For Medicare beneficiary A.V., on or around March 9, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

aa. For Medicare beneficiary K.B., on or around May 9, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

bb. For Medicare beneficiary K.B., on or around May 31, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

cc. For Medicare beneficiary K.B., on or around June 28, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

dd. For Medicare beneficiary K.B., on or around August 29, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

ee. For Medicare beneficiary K.B., on or around September 29, 2016, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

ff. For Medicare beneficiary K.B., on or around January 3, 2017, CPS billed the Medicare program \$754.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

gg. For Medicare beneficiary K.B., on or around February 6, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

hh. For Medicare beneficiary K.B., on or around March 9, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

ii. For Medicare beneficiary M.H., on or around May 30, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

jj. For Medicare beneficiary M.H., on or around June 27, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

kk. For Medicare beneficiary L.G., on or around June 27, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

ll. For Medicare beneficiary J.M., on or around May 23, 2017, CPS billed the Medicare program \$483.00 under CPT Code G0481 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

mm. For Medicare beneficiary T.P., on or around June 27, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

nn. For Medicare beneficiary D.P., on or around June 14, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

oo. For Medicare beneficiary D.P., on or around June 15, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative

screening for all drug classes came back negative.

pp. For Medicare beneficiary V.T., on or around March 3, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

qq. For Medicare beneficiary V.T., on or around March 3, 2017, CPS billed the Medicare program \$762.00 under CPT Code G0483 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

rr. For Medicare beneficiary V.T., on or around April 25, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

ss. For Medicare beneficiary V.T., on or around June 20, 2017, CPS billed the Medicare program \$613.00 under CPT Code G0482 for a CDDP panel, even though the qualitative screening for all drug classes came back negative.

56. Defendants gross approximately \$6 million per month from the Brentwood, Tennessee laboratory. Approximately 20% of this monthly revenue (\$1.2 million) comes from negative drug screenings unnecessarily being sent for a

CDDP panel and billed to the Medicare program.

FIRST CAUSE OF ACTION

(For presentation of false claims in violation of the False Claims Act, 31 U.S.C.

§ 3729(a)(1)/31 U.S.C. § 3729(a)(1)(A), against Defendants)

57. Plaintiffs re-allege and incorporate by reference each allegation in paragraphs 1 to 56 of this complaint.

58. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to the United States of America false or fraudulent Medicare and Medicaid claims for payment or approval, in violation of the False Claims Act.

59. Defendants' claims for payment or approval from the Medicare and Medicaid programs were false in that the clinical diagnostic laboratory tests claimed for were not reasonable and necessary. Defendants presented these claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

60. The United States of America, unaware of the falsity of the claims made or submitted by Defendants, paid and continues to pay Defendants for claims that would not be paid if the true facts were known.

61. As a proximate cause of Defendants' false claims, the United States of America has been damaged in an amount exceeding the jurisdictional limit, and to

be proven at trial.

SECOND CAUSE OF ACTION

(For using false statements to get false claims paid in violation of the False Claims Act, 31 U.S.C. § 3729(a)(2)/31 U.S.C. § 3729(a)(1)(B), against Defendants)

62. Plaintiffs re-allege and incorporate by reference each allegation in paragraphs 1 to 61 of this complaint.

63. By virtue of the acts described above, Defendants knowingly made or used false medical records or statements of medical necessity to get a false or fraudulent Medicare and/or Medicaid claim paid or approved by the United States of America, in violation of the False Claims Act.

64. The United States of America, unaware of the falsity of the statements or records material to the false claims made or submitted by Defendants, paid and continues to pay Defendants for claims that would not be paid if the true facts were known.

65. As a proximate cause of Defendants' false claims, the United States of America has been damaged in an amount exceeding the jurisdictional limit, and to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for judgment in their favor as follows:

1. For statutory damages in an amount to be established at trial, trebled as required by law, and such civil penalties as are allowed by law;
2. All costs and expenses of this action, including attorneys' fees, with pre- and post-judgment interest; and
3. For all other relief that the Court deems just and proper.

Dated: September 1, 2017

Respectfully Submitted,



Michael J. Khouri, Esq.
KHOURI LAW FIRM, APC
24012 Calle De La Plata, Suite 210
Laguna Hills, CA 92653
Phone: (949) 336-2433
Attorney for Plaintiffs-Relators
Cynthia Niendorff, Shannon Skipper,
and Russell Smith

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs demand a trial by jury in the above-entitled matter.

Dated: September 1, 2017

Respectfully Submitted,



Michael J. Khouri, Esq.
KHOURI LAW FIRM, APC
24012 Calle De La Plata, Suite 210
Laguna Hills, CA 92653
Phone: (949) 336-2433
Attorney for Plaintiffs-Relators
Cynthia Niendorff, Shannon Skipper,
and Russell Smith

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Date served: September 1, 2017

On **September 1, 2017**, I served the foregoing documents described as:

- [FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C.
§ 3730(b)(2)]

- WRITTEN DISCLOSURE TO UNITED STATES DEPARTMENT OF JUSTICE OF SUBSTANTIALLY ALL OF QUI TAM PLAINTIFFS' MATERIAL EVIDENCE AND INFORMATION PURSUANT TO 31 U.S.C. § 3730(b)(2)**

United States Attorney's Office
Knoxville Headquarters
Attention: Civil Division/Civil Process Clerk
800 Market Street, Suite 211
Knoxville, Tennessee 37902

1 Civil Process Clerk
2 U.S. Department of Justice, Office of the Attorney General
3 950 Pennsylvania Avenue, NW
4 Washington, DC 20530

5 in the following manner:

6 ☒ (BY CERTIFIED MAIL) I deposited such envelope in the mail at
7 Laguna Hills, California. The envelope was mailed with postage thereon fully
8 prepaid and return receipt requested.

9 ☐ (BY PERSONAL DELIVERY) I caused each envelope to be
10 delivered by hand to the office of the addressee.

11 ☐ (BY OVERNIGHT COURIER) I caused each envelope, with delivery
12 charges prepaid, to be sent by Overnite Express.

13 ☐ (BY TELEFACSIMILE) I caused the transmission of the above-
14 entitled document to the interested parties at the telefacsimile number listed on the
15 attached Service List on _____, at Laguna Hills, California.

16 I am "readily familiar" with the firm's practice of collection and processing
17 correspondence for mailing with the United States Postal Service. Under that
18 practice, on the above date the envelope was sealed and placed for collection and
19 mailing following the ordinary business practices of our office. This results in the
20 envelope being delivered to the United States Postal Service that same day, with
21 postage thereon fully prepaid. I am aware that on motion of the party served,
22 service is presumed invalid if postal cancellation date or postage meter date is
23 more than one day after the date of deposit for mailing in the affidavit.

24 Executed on **September 1, 2017**, at Laguna Hills, California.

25 I declare under penalty of perjury under the laws of the United States of
26 America that the above is true and correct.

27 

28 Andrew B. Goodman